

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

February 24, 2022

Memorandum:

Subject: Acute Toxicity Review for EPA File Symbol: 2749-ANO

Applicant: Aceto US, L.L.C.
Product Name: AG35814 R334.2 70 WP Insecticide
DP Barcode: D462400
Decision No.: 570823
Action Code: R334.2
PC Code(s): 099050 (Acetamiprid)

From: Odbert Triplett, Biologist
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Registration Division (7505P)

Through: Byron T. Backus, Ph.D., Biologist
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To: Ralph Narain
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Formulation from label:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Acetamiprid.....	70%
<u>Other Ingredients:</u>	30%
Total:	100%

ACTION REQUESTED: The Risk Manager requests a review of cited or submitted acute toxicity studies to support registration of AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO.

BACKGROUND: The registrant, Aceto US, L.L.C., has applied to register AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO, the proposed product contains the active ingredient Acetamiprid (70%). The registrant is claiming their product is similar or identical in composition and labeling to EPA Reg # 8033-23, Assail 70 WP Insecticide.

The Agency reviewed the data to assess the acute toxicity, irritation, and dermal sensitization potential of the proposed product (see Toxicity Profile under "Comments and Recommendations"). AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO, is a new end-use product with unregistered source(s) of active ingredient(s); The label of AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO, indicates that it is "For Agricultural Use Only."

The application package included a copy of both the proposed Basic and Alternate (Alt. 1) CSF dated January 31, 2021, both with Inerts Approved for Food Use under 40 CFR 180.910, Pre and Post Harvest Application.

The registrant is using the selective method of data support to satisfy five of the acute toxicity data requirements. The data matrix cites the following MRIDs: 44651821 acute oral (870.1100), 44651822 acute dermal (870.1200), 44651823 acute inhalation (870.1300), 44651825 primary dermal irritation (870.2500) and dermal sensitization (MRID 44651826). The registrant has also submitted MRID 51588301 a new eye irritation study (870.2400).

RECOMMENDATIONS:

1. After comparing the proposed Basic and Alternate (Alt. 1) CSFs (both dated January 31, 2021) for 2749-ANO with the accepted basic CSF for 8033-23 (dated 7/6/99, available on p. 1 of 651930_4_CSF.pdf) it is concluded the two formulations are toxicologically similar and have the same acute toxicity profile.
2. The cited studies in MRIDs 44651821 through -25 and -26 have been previously reviewed and classified as acceptable. (TXR 5004690, TRB memorandum dated June 3, 2002 for 264-ANT, subsequently transferred to 8033-22). These studies have been previously cited for actions involving 8033-23 (page 2 of the data matrix dated 12-20-12 for 8033-23 under 13 8570-35 WP.pdf; available in Documentum) and can be used to satisfy the appropriate acute toxicity data requirements for 2749-ANO.
3. As part of the current action, the eye irritation study in MRID 51588301 has been reviewed and classified as acceptable, with assignment of 2749-ANO to toxicity IV by this exposure route.
4. All acute toxicity data requirements for the registration of AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO have been satisfied by the cited studies (MRIDs 44651821 through -25 and -26) and the submitted eye irritation study (MRID 51588301).

5. Both the proposed Basic and Alternate (Alt. 1) CSF submitted for AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO, dated 01/31/21, must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.
6. The labeling submitted for this product is generally consistent with the cited label, except that for this product a few changes are noted below.
7. The registrant has included first aid statements for “if in eye” and “if inhaled”, this is acceptable. The preferred order is for the “if swallowed” to come before the “if on skin or clothing” first aid statement, then the “if inhaled” preceding the “if in eye”.
8. The registrant has added “Causes moderate eye irritation. Avoid contact with eyes, skin or clothing.” which is acceptable.
9. The registrant has added “Harmful if inhaled. Avoid breathing vapors or spray mist” this is acceptable.
10. The registrant states that a respirator should be worn for aerial applications, mixers and loaders. This is consistent with the last accepted (June 11, 2021) cited label for 8033-23 and is acceptable.
11. The registrant’s listing of Personal Protective Equipment is acceptable, although the statement to wear “Chemical resistant gloves made of the following waterproof material” could be revised to “Chemical resistant gloves” as one of the ingredients listed in the CSF requires solvent category C gloving (LRM, pg. 10-9). Additionally, while the gloves listed are acceptable, Butyl Rubber \geq 14 mils could be added to the listing.
12. The Agency can accept the precautionary and first aid labeling statements for 2749-ANO as proposed by the registrant.
13. The following constitutes the toxicology profile assigned to AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO:

Acute oral toxicity	cited	III	MRID	44651821
Acute dermal toxicity	cited	III	MRID	44651822
Acute inhalation toxicity	cited	IV	MRID	44651823
Primary eye irritation	acceptable	IV	MRID	51588301
Primary dermal	cited	IV	MRID	44651825
Dermal sensitization	cited	negative	MRID	44651826

Based on the acute toxicity profile given above, the following are the precautionary and first aid labeling statements for AG35814 R334.2 70 WP Insecticide, EPA File Symbol: 2749-ANO, as obtained from the Label Review System:

Product ID: 2749-ANO

Product Name: AG35814 R334.2 70 WP Insecticide

Precautionary Statements:

Keep out of Reach of Children.

Signal Word: **CAUTION**

Poison Label: **None**

The use of “Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.) is acceptable.

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Harmful if absorbed through skin.

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and (waterproof or chemical-resistant) gloves. Remove and wash contaminated clothing before reuse.

Additional labeling should include (but not necessarily be limited to) the following:

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

The registrant has added “Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them” to the label and this is acceptable.

User Safety Recommendations

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing

The registrant has added “Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet” to the User Safety Recommendations and this is acceptable.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.

- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

The Note to Physician suggested by the registrant is acceptable.

EPA encourages but does not require (see PR Notice 2001-1) registrants to include a company telephone number or toll-free hotline for emergency information in the first aid section. The following are examples of appropriate statements that may be included on the label:

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222. For general information about this product, call 1-XXX-XXX-XXXX [may include hours of service], or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at <http://npic.orst.edu>.

The proposed label includes a telephone number and a statement to have the product container and label when calling to a poison control center or doctor, along with a contact phone number for emergency medical information. These statements are appropriate and acceptable.

DATA EVALUATION RECORD

AG35814 R334.2 70 WP INSECTICIDE (AG3581470 WP)

STUDY TYPE: ACUTE EYE IRRITATION - RABBIT [OCSPP 870.2400; OECD 405]

MRID 51588301

Prepared for
Registration Division
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U.S. Environmental Protection Agency
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Prepared by
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Task Order No. AcuteTox-4-112

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-16-019

DATA EVALUATION RECORD

Reviewers: Odbert Triplett, Biologist, CITAB
Donna L. Fefee, DVM (Summitec Corp.)

Date: February 24, 2022

Product Reg. No./File Symbol: 2749-ANO

1. DP BARCODE: 462400				
2. PC CODE: 099050				
3. CURRENT DATE: February 24, 2022				
4. TEST MATERIAL: AG35814 70WP: 70% Acetamiprid; Lot no. 102720A; PSL Reference no.: 201030-9H; off-white powder; density: not reported; pH: not reported; expiration date: October 26, 2022; stored at room temperature and expected to be stable for the duration of testing.				
Study/Strain & Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Primary eye irritation/New Zealand albino rabbit Product Safety Labs (Dayton, New Jersey) Study no. 54317 May 24, 2021 OCSPP 870.2400; OECD 405	51588301	Minimally irritating; MMTS = 2.7 (at 1 hour) One-tenth of a milliliter (0.022 g) of the undiluted powdery test substance was instilled into the anesthetized (with tetracaine HCl) right eye of 3 young adult female rabbits. Systemic analgesia was also provided. Corneal opacity, iritis, and discharge were not seen in the study. At one hour post instillation, 2/3 eyes had "non-positive" conjunctival redness and chemosis (scores=1), and the remaining eye was normal. All eyes were normal at 24, 48, and 72 hours. There were no abnormal systemic clinical signs, and all animals gained weight during the study.	IV	A

*Core Grade Key: A =Acceptable; S = Supplementary; U = Unacceptable; D = Data Gap; W = Waived